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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:

Harold I. NYLAND et al

Conf. No.: **8578**

Serial No.: **09/599,002**

Group Art Unit: **1655**

Filed: **June 22, 2000**

Examiner: **Johannsen, D.**

For: **METHOD FOR DISEASE DIAGNOSIS BASED ON Fc RECEPTOR GENOTYPING**

RESPONSE TO SECOND RESTRICTION REQUIREMENT

Assistant Commissioner
of Patents
Washington, D.C. 20231

Sir:

This Response to Second Restriction Requirement is in reply to the Office Action dated January 2, 2002, in the above-identified application, for which Petition for a Two-Month Extension of Time, along with payment of the appropriate fee. is attached, making response due on or before April 2, 2002.

The Patent Office is authorized to charge any fees necessary for the continued pendency of the above-identified application to our Deposit Account No. 19-4880.

Accordingly, please amend the above-identified application as follows.

IN THE CLAIMS:

Please cancel Claims 33-35.

REMARKS

In paragraph 2, on page 2 of the Office Action, the Examiner has issued a Restriction Requirement under 35 U.S.C. § 121 to one of the inventions of the following groups:

Group I - Claims 15-24, 28 and 30-32, drawn to methods of disease prognosis;

Group II - Claims 25 and 29, drawn to methods of therapy comprising surgical intervention;

Group III - Claims 26-27, drawn to methods of therapy comprising administering a prophylatic or therapeutic agent; and

Group IV - Claims 33-35, drawn to a kit comprising an "allele specific binder".

Specifically, the Examiner states that the inventions of Groups I, II and III are patentably distinct methods having different effects requiring different process steps and employing different reagents, i.e., the invention of Group I requires a step of determining genotype; the invention of Group II requires a step of surgery to achieve the effect of intervention against diseases; and the invention of Group III requires a step of administering an agent to achieve the effect of non-surgical disease therapy or prevention.

Further, the Examiner states that the inventions of Groups I and IV, II and IV, and III and IV are related as product and process of use, and in the present case, the "allele specific binder" of the invention of Group IV may be used in a process that is materially different from that of the inventions

of Groups I, II and III, such as in nucleic acid sequencing or synthesis.

Applicants hereby elect the invention of Group I with traverse with respect to the inventions of Groups II and III. Applicants hereby cancel Claims 33-35 of non-elected Group IV without prejudice to the filing of a Divisional Application with respect thereto.

Applicants respectfully submit that the Examiner's restriction is improper as between the inventions of Groups I-III since the inventions of Groups II and III both require carrying out the genotyping steps of the invention of Group I. Group I is generic and covers carrying out subsequent additional steps, e.g., as recited in Groups II and III. Hence, all three groups require carrying out genotyping and thus require at least some of the same steps. The Examiner has failed to provide any rationale as to why the subsequent additional steps recited in Groups II and III provide a patentable distinction, much less require an undue search burden, as is required by MPEP § 803 for restriction to be proper. Thus, the Examiner is requested to withdraw the Restriction Requirement as between Groups I-III.

In paragraph 4, on page 3 of the Office Action, the Examiner issues an Election of Species Requirement to one of the following species:

(a) Multiple distinct diseases as set forth in Claims 15 and 30, and genotypes associated therewith as set forth in Claims 18-22; and

(b) Multiple distinct "allele specific binders" or combinations thereof encompassed by Claims 33-35.

Specifically, if any of the inventions of Groups I-III are elected, the Examiner requires Applicants to elect for prosecution, one specific disease and one specific genotype or combination of genotypes associated with the specific disease; or if the invention of Group IV is elected, the Examiner requests Applicants to elect a specific "allele specific binder" or combination thereof.

Accordingly, since Applicants have elected the invention of Group I with traverse with respect to the inventions of Groups II and III, Applicants hereby elect multiple sclerosis as the disease, and genotyping the FcγRIIA and/or FcγRIIIB receptors associated with said disease. If the Examiner seeks election of a more specific genotype, then Applicants elect the genotype recited in Claim 18.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

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